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10/079,063	02/19/2002	Alastair Hodges	USFSEN.078C2	5939

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/079,063		HODGES ET AL.	
	Examiner		Art Unit	
	ALEX NOGUEROLA		1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 and 19 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/659,470.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>05242002</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky et al. (US 5,128,015) ("Szuminsky").

Claim 3 of U.S. Patent No. 6,475,360 B1 contains all the limitations of claim 1 of the instant application except for having the "means for measuring a concentration of an analyte or a concentration of a species representative of the analyte in the sample at a point on a reaction profile" measure "amperometrically a parameter representative of a diffusion coefficient of the analyte or the species representative of the analyte in the sample." Szuminsky discloses an electrochemical cell having a spacer between opposing electrodes (abstract and Figures 1, 4, and

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5). Szuminsky further discloses means for measuring a concentration of an analyte or a concentration of a species representative of the analyte in the sample at a point on a reaction profile by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte or the species representative of the analyte in the sample (implied by Figure 8; col. 3, ln. 46 – col. 4, ln. 6; and col. 4, ln. 57 – col. 5, ln. 13, which together disclose making a concentration measurement of the analyte by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide means for making a concentration measurement of the analyte or a species representative of the analyte in the sample by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte or the species representative of the analyte in the sample as taught by Szuminsky in the invention of claim 3 of U.S. Patent No. 6,475,360 B1 because as taught by Szuminsky “[m]easurements by the method according to the present invention of the current due to reoxidation of the acceptors were found to be proportional to the glucose concentration in the sample” (col. 4, ll. 2-6) and “the measurement system ... eliminates several of the critical operator dependent variables that adversely affect the accuracy and reliability and provides for a greater dynamic range than other self-testing systems’ (col. 5, ll. 14-18).

3. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 12 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1, from which claim 2 depends, has been addressed above. Claim 12 of U.S. Patent No. 6,475,360 B1 provides an electrically resistive element as required by claim 2.

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4. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 3 of the instant application depends, has been addressed above. The means of claim 3 of the instant application appears to have already been provided by claim 1 of the instant application (see the rejection under 35 U.S.C. 112, second paragraph, below). Thus, claim 3 of the instant application is obvious over claim 3 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky for the same reasons that claim 1 of the instant application is obvious over claim 3 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky.

5. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 4 of the instant application depends, has been addressed above. Claim 4 of U.S. Patent No. 6,475,360 B1 requires the predetermined point on the reaction profile to be a steady state (also note Figure 8 in Szuminsky).

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6. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 5 of the instant application depends, has been addressed above. Claim 5 of U.S. Patent No. 6,475,360 B1 requires a mediator as claimed (also note col. 4, ll. 16-45 in Szuminsky).

7. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 5 of the instant application, from which claim 6 of the instant application depends, has been addressed above. Claim 6 of U.S. Patent No. 6,475,360 B1 requires a mediator as claimed (also note col. 4, ll. 16-45 in Szuminsky).

8. Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 7 of the instant application depends, has been addressed above. Claim 7 of U.S. Patent No. 6,475,360 B1 requires at least one suitable reagent to be salt which liberates heat on dissolution. This salt will function as required by the suitable reagent of claim 7 of the instant application.

9. Claim 8 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 7 of the instant application, from which claim 8 of the instant application depends, has been addressed above. Claim 7 of U.S. Patent No. 6,475,360 B1 requires at least one suitable reagent to be salt which liberates heat on dissolution.

10. Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 8 of the instant application, from which claim 9 of the instant application depends, has been addressed above. Claim 9 of U.S. Patent No. 6,475,360 B1 requires the salt to be selected from the same Markush group as claim 9 of the instant application.

11. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 18 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 7 of the instant application, from which claim 10 of the instant application depends, has been addressed above. Claim 18 of U.S. Patent No. 6,475,360 B1 requires the electrochemical cell to also comprise an enzyme. It is clear from the specification that the enzyme is a reagent component.¹

¹ The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). MPEP 804.

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12. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 9, and 18 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 10 of the instant application, from which claim 11 of the instant application depends, has been addressed above. Claim 9 of U.S. Patent No. 6,475,360 B1 requires each of the two components to be placed in separate locations in the electrochemical cell.

13. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 10, and 18 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 11 of the instant application, from which claim 12 of the instant application depends, has been addressed above. Claim 10 of U.S. Patent No. 6,475,360 B1 requires the two components to be placed as coatings upon opposite internal cell walls of the electrochemical cell.

14. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 11 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 13 of the instant application depends, has been addressed above. Claim 11 of U.S. Patent No. 6,475,360 B1 requires an electrical heater as required by claim 13.

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15. Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 12 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 13 of the instant application, from which claim 14 of the instant application depends, has been addressed above. Claim 12 of U.S. Patent No. 6,475,360 B1 requires heating means having resistive elements as required by claim 14.

16. Claim 15 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 13 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 15 of the instant application depends, has been addressed above. Claim 13 of U.S. Patent No. 6,475,360 B1 requires heating means to have the capability required by claim 15.

17. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 14 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 16 of the instant application depends, has been addressed above. Claim 14 of U.S. Patent No. 6,475,360 B1 requires the heating means to have the capability required by claim 16.

18. Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 15 of U.S. Patent No. 6,475,360 B1 in view of

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Szuminsky. Claim 1 of the instant application, from which claim 17 of the instant application depends, has been addressed above. Claim 15 of U.S. Patent No. 6,475,360 B1 requires the heating means to have the capability required by claim 17.

19. Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 16 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 18 of the instant application depends, has been addressed above. Claim 16 of U.S. Patent No. 6,475,360 B1 requires the electrochemical cell to comprise a glucose sensor.

20. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 17 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 19 of the instant application depends, has been addressed above. Claim 17 of U.S. Patent No. 6,475,360 B1 requires the electrochemical cell to comprise a glucose sensor capable of measuring glucose in a blood sample.

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21. Claim 20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 18 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 20 of the instant application depends, has been addressed above. Claim 18 of U.S. Patent No. 6,475,360 B1 requires the electrochemical cell to comprise an enzyme.

22. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 19 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 20 of the instant application, from which claim 21 of the instant application depends, has been addressed above. Claim 19 of U.S. Patent No. 6,475,360 B1 requires the enzyme to comprise glucose dehydrogenase.

23. Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 20 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 20 of the instant application, from which claim 22 of the instant application depends, has been addressed above. Claim 20 of U.S. Patent No. 6,475,360 B1 requires the electrochemical cell to comprise an oxidizing mediator.

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24. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 21 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 20 of the instant application, from which claim 22 of the instant application depends, has been addressed above. Claim 21 of U.S. Patent No. 6,475,360 B1 requires the oxidizing mediator to comprise ferricyanide.

25. Claim 24 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 22 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 1 of the instant application, from which claim 24 of the instant application depends, has been addressed above. Claim 22 of U.S. Patent No. 6,475,360 B1 requires the means to further comprise a resistive element.

26. Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 23 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 24 of the instant application, from which claim 25 of the instant application depends, has been addressed above. Claim 23 of U.S. Patent No. 6,475,360 B1 requires the means for applying a potential across the resistive element to generate an amount of heat.

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27. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 24 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 25 of the instant application, from which claim 26 of the instant application depends, has been addressed above. Claim 24 of U.S. Patent No. 6,475,360 B1 requires means for interrupting the potential and applying a potential as required by claim 26 of the instant application.

28. Claim 27 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 24, and 25 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 26 of the instant application, from which claim 27 of the instant application depends, has been addressed above. Claim 25 of U.S. Patent No. 6,475,360 B1 requires means of applying a potential across the resistive element to have the capability required by claim 27 of the instant application.

29. Claim 28 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 24, and 26 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 26 of the instant application, from which claim 28 of the instant application depends, has been addressed above. Claim 26 of U.S. Patent No. 6,475,360 B1 requires means of applying a potential across the resistive element to have the capability required by claim 28 of the instant application.

30. Claim 29 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 24, 26, and 27 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky. Claim 28 of the instant application, from which claim 29 of the instant application depends, has been addressed above. Claim 27 of U.S. Patent No. 6,475,360 B1 requires the power output to have the capability required by claim 28 of the instant application.

31. Claim 30 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 3 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky et al. (US 5,128,015) ("Szuminsky").

Claims 2 and 3 of U.S. Patent No. 6,475,360 B1 together contain all the limitations of claim 30 of the instant application except for having the measuring circuit amperometrically measure "a parameter representative of a diffusion coefficient of an analyte or a species representative of the analyte in the sample, wherein the diffusion coefficient is indicative of a concentration of the analyte or the species representative of the analyte in the sample." Szuminsky discloses an electrochemical cell having a spacer between opposing electrodes (abstract and Figures 1, 4, and 5). Szuminsky further discloses a measuring circuit for measuring a concentration of an analyte or a concentration of a species representative of the analyte in the sample at a point on a reaction profile by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte or the species representative of the analyte in the sample (implied by Figure 8; col. 3, ln. 46 – col. 4, ln. 6; and col. 4, ln. 57 – col. 5, ln. 13, which together disclose making a concentration measurement of the analyte by measuring amperometrically a

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parameter representative of a diffusion coefficient of the analyte). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a measuring circuit for making a concentration measurement of the analyte or a species representative of the analyte in the sample by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte or the species representative of the analyte in the sample as taught by Szuminsky in the invention of combined claims 2 and 3 of U.S. Patent No. 6,475,360 B1 because as taught by Szuminsky “[m]easurements by the method according to the present invention of the current due to reoxidation of the acceptors were found to be proportional to the glucose concentration in the sample” (col. 4, ll. 2-6) and “the measurement system ... eliminates several of the critical operator dependent variables that adversely affect the accuracy and reliability and provides for a greater dynamic range than other self-testing systems” (col. 5, ll. 14-18).

32. Claim 31 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 7 of U.S. Patent No. 6,475,360 B1 in view of Szuminsky et al. (US 5,128,015) (“Szuminsky”).

Claims 3 and 7 of U.S. Patent No. 6,475,360 B1 together contain all the limitations of claim 31 of the instant application (that the salt of claim 7 liberates heat upon dissolution implies an exothermic reaction upon contact with the sample) except for having the measuring circuit amperometrically measure “a parameter representative of a diffusion coefficient of an analyte or a species representative of the analyte in the sample, wherein the diffusion coefficient is

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indicative of a concentration of the analyte or the species representative of the analyte in the sample.” Szuminsky discloses an electrochemical cell having a spacer between opposing electrodes (abstract and Figures 1, 4, and 5). Szuminsky further discloses a measuring circuit for measuring a concentration of an analyte or a concentration of a species representative of the analyte in the sample at a point on a reaction profile by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte or the species representative of the analyte in the sample (implied by Figure 8; col. 3, ln. 46 – col. 4, ln. 6; and col. 4, ln. 57 – col. 5, ln. 13, which together disclose making a concentration measurement of the analyte by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a measuring circuit for making a concentration measurement of the analyte or a species representative of the analyte in the sample by measuring amperometrically a parameter representative of a diffusion coefficient of the analyte or the species representative of the analyte in the sample as taught by Szuminsky in the invention of combined claims 3 and 7 of U.S. Patent No. 6,475,360 B1 because as taught by Szuminsky “[m]easurements by the method according to the present invention of the current due to reoxidation of the acceptors were found to be proportional to the glucose concentration in the sample” (col. 4, ll. 2-6) and “the measurement system ... eliminates several of the critical operator dependent variables that adversely affect the accuracy and reliability and provides for a greater dynamic range than other self-testing systems’ (col. 5, ll. 14-18).

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Claim Rejections - 35 USC § 112

33. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: it is not clear how this claim further modifies claim 1 as the means provided by claim 3 appears to have already been provided by claim 1.

Information Disclosure Statement

34. Applicant is request to provide a copy of the Japan Patent Abstract for 59-3345 A, which was cited on sheet 3 of the IDS ("IDS") of May 24, 2002 and which is missing from the file of the parent application, no.09/659,470. Applicant should also note that WO 97/18465 has been cited twice on sheet 4 of the IDS, but only initialed once.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
August 18, 2004